

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,  
Plaintiff,

v.

CIVIL ACTION NO. 3:17-01362

AMERISOURCEBERGEN  
DRUG CORPORATION, et  
al.,  
Defendants.

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CABELL COUNTY COMMISSION,  
Plaintiff,

v.

CIVIL ACTION NO. 3:17-01665

AMERISOURCEBERGEN  
DRUG CORPORATION, et  
al.,  
Defendants.

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**REPLY IN SUPPORT OF DEFENDANTS'  
MOTION FOR SUMMARY JUDGMENT FOR FAILURE TO  
PROVE FAULT ELEMENT OF PUBLIC NUISANCE CLAIMS**

## TABLE OF CONTENTS

	<b>Page</b>
INTRODUCTION .....	1
ARGUMENT .....	2
I.    To Establish Public Nuisance Liability, Plaintiffs Must Prove Defendants’ Conduct Was Either Intentional or Negligent, and Not Merely That the Conduct Was “Unlawful” .....	2
II.   Plaintiffs Have No Evidence That Defendants Acted Intentionally—That Is, With the Purpose of Harm or With Knowledge That Harm Was Resulting, or Was Substantially Certain To Result, From Their Conduct.....	4
III.  Plaintiffs Cannot Establish Negligence by Pointing To Alleged Violations of the CSA.....	8
A.   The CSA May Not Be Privately Enforced—Neither Directly Nor Through a State Common Law Claim .....	9
B.   The CSA and Its Associated Regulations Do Not Impose Duties on the Defendants, Let Alone a Duty Not to Ship Suspicious Orders.....	111
C.   Plaintiffs’ Claims are Preempted by the CSA.....	133
CONCLUSION.....	155

## TABLE OF AUTHORITIES

	Page(s)
<b>Cases</b>	
<i>Astra USA, Inc. v. Santa Clara Cty.</i> , 563 U.S. 110 (2011).....	9, 10, 11
<i>Bean v. Upsher-Smith Pharm., Inc.</i> , No. 4:16-CV-01696-RBH, 2017 WL 4348330 (D.S.C. Sept. 29, 2017) <i>aff'd</i> , 765 F. App'x 934 (4th Cir. 2019).....	15
<i>Buckman Co. v. Plaintiffs' Legal Committee</i> , 531 U.S. 341 (2001).....	13, 14, 15
<i>Duff v. Morgantown Energy Associates</i> , 187 W.Va. 712, 421 S.E.2d 253 (1992).....	2
<i>E.R. Presidents Conference v. Noerr Motor Freight, Inc.</i> , 365 U.S. 127 (1961).....	6
<i>Flanagan v. Gregory &amp; Poole</i> , 136 W. Va. 554, 67 S.E.2d 865 (1951).....	4
<i>Floyd v. Feygin</i> , No. 507458/17, 2018 WL 6528728 (N.Y. Sup. Ct. Dec. 6, 2018) .....	9
<i>Geier v. Am. Honda Motor Co.</i> , 529 U.S. 861 (2000).....	14, 15
<i>Gonzalez v. Raich</i> , 545 U.S. 1 (2005).....	12, 13
<i>Hendricks v. Stalnaker</i> , 181 W.Va. at 35, 380 S.E.2d at 202.....	4
<i>McDaniel v. Upsher-Smith Labs., Inc.</i> , 893 F.3d 941 (6th Cir. 2018), <i>cert. denied</i> , No. 19-1246, 2020 WL 5882237 (U.S. Oct. 5, 2020).....	15
<i>McKesson Corp. v. Hembree</i> , No. 17-CV-323-CK-FHM, 2018 WL 340042 (N.D. Okla. Jan. 9, 2018).....	9
<i>Myers v. United States</i> , 17 F.3d 890 (6th Cir. 1994) .....	10
<i>Nathan Kimmel, Inc. v. DowElanco</i> , 275 F.3d 1199 (9th Cir. 2002) .....	15

<i>Nw. Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO</i> , 451 U.S. 77 (1981).....	12
<i>Opdyke Inv. Co. v. City of Detroit</i> , 883 F.2d 1265 (6th Cir. 1989) .....	7
<i>Sharon Steel Corp. v. City of Fairmont</i> , 175 W.Va. 479, 334 S.E.2d 616 (1985).....	2
<i>Sierra Club v. Butz</i> , 349 F. Supp. 934 (N.D. Cal. 1972) .....	7
<i>Smith v. Hickenlooper</i> , 164 F. Supp. 3d 1286 (D. Colo. 2010).....	9
<i>West Virginia v. McKesson Corp.</i> , Case No. 2:17-03555, Dkt. 21 (S.D. W. Va. Feb. 15, 2018) .....	9
<i>Wyeth v. Levine</i> , 555 U.S. 555 (2009).....	13

## **Statutes**

21 U.S.C. § 823(b) .....	11
W. Va. C.S.R. § 15-2-3.....	12
W. Va. C.S.R. § 15-2-4.....	12
W.Va. Code § 17-23-9 .....	3
W.Va. Code § 30-7-14.....	3
W.Va. Code § 60-6-16.....	3

## **Regulations**

21 C.F.R. §§ 1300–1321 .....	12
21 C.F.R. § 1301.01 .....	11
21 C.F.R § 1301.71(a).....	11

**Other Authorities**

DEA, *Practitioner’s Manual, An Informational Outline of the Controlled Substances Act* 4 (2006 ed.) .....10

Restatement (Second) of Torts § 821B .....2, 3, 4

Restatement (Second) of Torts § 825.....4

## INTRODUCTION

Plaintiffs’ contention that they need prove only that Defendants acted “unlawfully” to establish the fault element of their nuisance claims is contrary to West Virginia law and the Restatement (Second) of Torts. Because Plaintiffs are not suing pursuant to a general ordinance or statute that declares Defendants’ alleged conduct to be a nuisance, controlling law requires Plaintiffs to prove fault—and, to do that, they must establish intentional or negligent conduct. Moreover, even if, as Plaintiffs suggest, West Virginia law authorizes nuisance liability to be imposed based on any unlawful act (it does not), federal law nonetheless bars Plaintiffs’ efforts to use standards allegedly contained in the Controlled Substances Act (“CSA”) to impose tort liability on Defendants.

Plaintiffs offer no evidence that Defendants acted intentionally—because there is none. There is no evidence that Defendants acted for the purpose of causing addiction, overdoses, or other harms in Cabell/Huntington or that such addiction, overdoses, or other harms were substantially certain to result. Even today, Plaintiffs’ experts have failed to provide any basis to conclude that opioid medications in any particular shipments were diverted to illicit use. Thus, Plaintiffs have no evidence that Defendants did anything other than ship orders placed by licensed pharmacies and hospitals to fill valid prescriptions written by physicians based on the then-prevailing standard of care. Plaintiffs therefore cannot establish that Defendants intended to create a public nuisance or knew that a public nuisance was substantially certain to result from their conduct.

Nor can Plaintiffs prove fault through a negligence theory. Plaintiffs’ dependence on the federal CSA to establish that Defendants acted negligently is fatal to their claims. Plaintiffs acknowledge that they may not bring suit under the CSA. Yet they contend they may use the CSA’s regulatory provisions to establish unreasonableness, unlawfulness, negligence, or

breach of some other common-law duty. As a matter of law, they cannot. Unless Congress has authorized private enforcement of a federal statute, federal law prohibits such enforcement—both direct and indirect. Allowing Plaintiffs to use the CSA to establish a breach of common law is functionally equivalent to allowing Plaintiffs to bring suit under the CSA itself. That would amount to an impermissible end-run around Congress’s judgment that the CSA may not be privately enforced. The same is true when it comes to Plaintiffs’ invocation of the West Virginia Controlled Substances Act.

### ARGUMENT

#### **I. To Establish Public Nuisance Liability, Plaintiffs Must Prove Defendants’ Conduct Was Either Intentional or Negligent, and Not Merely That the Conduct Was “Unlawful”**

As explained in Defendants’ opening brief, the Supreme Court of Appeals of West Virginia has recognized that West Virginia’s definition of a public nuisance “is consistent with Restatement (Second) of Torts § 821B(1) (1979), which defines public nuisance as ‘an unreasonable interference with a right common to the general public.’”<sup>1</sup> The Restatement establishes that a plaintiff can prove an unreasonable interference by proving either intentional and unreasonable or negligent conduct:

[T]he defendant is held liable for a public nuisance if his interference with the public right was intentional or was unintentional and otherwise actionable under the principles controlling liability for negligent or reckless conduct or for abnormally dangerous activities.<sup>2</sup>

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<sup>1</sup> *Duff v. Morgantown Energy Associates*, 187 W.Va. 712, 716 n.6, 421 S.E.2d 253, 257 n.6 (1992); *see also Sharon Steel Corp. v. City of Fairmont*, 175 W.Va. 479, 483, 334 S.E.2d 616, 620 (1985).

<sup>2</sup> Restatement (Second) of Torts § 821B, cmt. e. Comment e notes that the analysis for public nuisance is similar to the analysis for private nuisance.

Plaintiffs try to avoid the fault element altogether by arguing that a public nuisance claim can be based on merely unlawful conduct, regardless of fault.<sup>3</sup> And, in support of this proposition, Plaintiffs rely upon § 821B(2)(b), which states: “(2) Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following: ... (b) whether the conduct is proscribed by a statute, ordinance or administrative regulation ....”<sup>4</sup>

But Plaintiffs read that provision too broadly. It does not establish that the element of unreasonableness can be proven by showing the violation of any statute or regulation. Instead, this provision refers only to instances where “particular conduct is declared to be a public nuisance by a specific statute, an ordinance, or an administrative regulation.”<sup>5</sup> The law might support that proposition *if* there were a statute expressly declaring Defendants’ conduct to be a public nuisance. In those limited situations, the law dispenses with the need to prove the

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<sup>3</sup> Doc. 1075 at p.2; Plaintiffs’ Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims (“Plaintiffs’ Opp.”); *see also id.* at p.15 (arguing that “Defendants may be held liable in nuisance if their conduct was unlawful, regardless of whether it was also negligent [or intentional]”).

<sup>4</sup> Restatement (Second) of Torts § 821B(2)(b).

<sup>5</sup> *Id.* § 821B, cmt. e (“If, however, particular conduct is declared to be a public nuisance by a specific statute, an ordinance, or an administrative regulation, the act may provide, or be construed to mean, that the defendant is guilty of the crime even though his interference was purely accidental and unintentional.”). Subject to constitutional limitations, the West Virginia Legislature has the prerogative to declare by statute that certain places, things, or conduct constitute a public nuisance, and the West Virginia Codes contains examples of this. *See, e.g.*, W.Va. Code § 17-23-9 (“The establishment, operation or maintenance of a salvage yard or any part thereof in violation of any provision of this article is hereby declared to be a public nuisance, ....”); *id.* § 60-6-16 (“A place where alcoholic liquor is manufactured, sold, stored, possessed, given away, or furnished contrary to law shall be deemed a common and public nuisance.”); *id.* § 30-7-14 (“The practice of registered professional nursing by any person who has not been licensed ..., is hereby declared to be inimical to the public health and welfare and to be a public nuisance.”).



defendant's conduct was intentional or negligent.<sup>6</sup> Here, however, there is *no statute or regulation* expressly declaring the conduct on which Plaintiffs base their claims to be a public nuisance.<sup>7</sup>

Thus, we are back to where we started—Plaintiffs must prove conduct that was either intentional or negligent. They cannot.

## **II. Plaintiffs Have No Evidence That Defendants Acted Intentionally—That Is, With the Purpose of Harm or With Knowledge That Harm Was Resulting, or Was Substantially Certain To Result, From Their Conduct**

An interference with a public right is intentional if the defendant “acts for the purpose of causing [the consequence of his act]” or “knows that [the consequence] is resulting or is substantially certain to result from his conduct.”<sup>8</sup> Plaintiffs claim they have ample evidence of intentional conduct. Plaintiffs, however, have not identified any evidence showing that Defendants acted with an intent to bring about a crisis of opioid misuse and addiction, or any other harms. Nor have they presented any evidence that Defendants knew that such a crisis was substantially certain to result from their conduct.

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<sup>6</sup> Restatement (Second) of Torts § 821B.

<sup>7</sup> And, while Section 821B(2)(b) states that whether the conduct is proscribed by a statute, ordinance, or administrative regulation may be a *factor* in determining whether the interference was *unreasonable*, a mere violation of some law is not sufficient to *establish intent*. Moreover, as the Supreme Court of Appeals made clear in *Hendricks v. Stalnaker*, 181 W.Va. at 35, 380 S.E.2d at 202, establishing a violation of a statute does not dispense with the need to prove intentional conduct or negligence. Plaintiffs contend that *Flanagan v. Gregory & Poole*, 136 W. Va. 554, 562, 67 S.E.2d 865, 871 (1951), holds that creation of a nuisance constitutes violation of an absolute duty. While *Flanagan* says that, the Court ultimately held that the conduct must be wrongful for liability to attach for nuisance. *Id.* And, importantly, Plaintiffs' assertion that *Flanagan* holds that existence of a nuisance relieves the plaintiff from an obligation to prove fault is wholly inconsistent with the standard later adopted in *Hendricks* and described by the Restatement.

<sup>8</sup> Restatement (Second) of Torts § 825.

Plaintiffs contend that Defendants’ conduct became “intentional” when Defendants “became aware of diversion resulting from their suspicious order monitoring (“SOM”) system failures.”<sup>9</sup> However, allegations that Defendants should have reported more orders as suspicious or declined to ship certain orders does not prove intentional conduct. Moreover, none of Plaintiffs’ experts identified any orders based on prescribing that Defendants should have recognized as inappropriate under the then-prevailing standard of care. Nor did they identify any shipments by Defendants that were actually diverted or that led to any harm. Thus, Plaintiffs have no evidence that the orders shipped by Defendants were improper—let alone of any shipments that Defendants knew were substantially certain to be diverted and cause harm.<sup>10</sup>

Plaintiffs cite a number of excerpts from the record in an effort to prove that Defendants acted intentionally. On inspection, these excerpts have nothing to do with Defendants’ intent. These excerpts can broadly be categorized into three groups.

**First**, Plaintiffs note that the Defendants were subject to federal DEA settlements and enforcement actions.<sup>11</sup> But evidence of settlements by Defendants is inadmissible to prove liability.<sup>12</sup> And, even if they were admissible, those settlements do not speak to whether—much less provide evidence that—Defendants acted with the *purpose* to bring about the condition of a widespread addiction crisis, or that Defendants intended to cause even one

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<sup>9</sup> Doc. 1075 at p.3, Plaintiffs’ Opp.

<sup>10</sup> *See, e.g.*, Ex. A (Rafalski Dep.) at 90:13-23 (“Q. Did you look at any of those tens of millions of orders in terms of the actual facts of those orders ... you believe that order is likely to be diverted? A. I cannot definitively look at one specific order and tell you that specific order was diverted ... I did not do that and I could not do that.”).

<sup>11</sup> Doc. 1075 at p.7, Plaintiffs’ Opp.

<sup>12</sup> Defendants have filed a motion in limine to exclude this improper evidence, and Defendants incorporate that argument here. Doc. 1067 at pp.11-15, Defendants’ Motions in Limine.

person to become addicted to or misuse opioids, or that Defendants acted with knowledge that those harms were substantially certain to result from their conduct.

**Second**, Plaintiffs point to experts who speak about Defendants' SOM systems and the volume of prescription opioids they distributed. But even if these experts' methodologies were reliable (they are not), and their testimony were relevant (it is not), nothing about testimony concerning the adequacy of the SOM systems is evidence that Defendants acted with the ***purpose*** of causing harm or with ***knowledge*** that a harm was substantially certain to result from their conduct. In fact, as noted, Plaintiffs' experts acknowledged that they do not know whether a single order was suspicious, diverted, or caused any harm anywhere, much less in Huntington/Cabell. If the experts cannot say even today that Defendants' actions caused harm, they certainly cannot say that Defendants knew that harm in Huntington/Cabell was substantially certain to result at the time their shipments were made.

**Third**, Plaintiffs point to statements made by Defendants' employees in depositions that hypothetical failures to follow procedures might increase the likelihood of diversion, that diversion "can happen" if laws are not followed, and "diversion could occur" if distributors do not adhere to effective controls. But these general statements do not relate to any actual failures by a Defendant. A general acknowledgement that a hypothetical failure to follow laws and procedures ***might*** lead to diversion is not the same as an acknowledgement that Defendants' conduct in fact was resulting in, or was substantially certain to result in, any harm.<sup>13</sup>

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<sup>13</sup> Plaintiffs also cite evidence that Plaintiffs say shows that Defendants allegedly made efforts through third parties to influence regulatory policy and public perception of the opioid crisis. In addition to being irrelevant to the question of intent, any such conduct cannot form the basis for liability because it is immunized under the First Amendment's *Noerr-Pennington* doctrine. The *Noerr-Pennington* doctrine—which derives from *United Miner Workers v. Pennington*, 381 U.S. 657 (1965), and *E.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961)—protects persons from liability for their speech and conduct in exercising their

*Finally*, Plaintiffs’ assertion that the opioid epidemic was the necessary consequence of Defendants shipping too many pills does not amount to proof of intent. At the time the shipments were made, the evidence shows that the increases in pharmacy orders were driven by increases in prescriptions based on a change in the standard of care for the treatment of chronic pain. Thus, evidence that Defendants knew the volume of shipments was increasing does not shown an intent to cause injury, but is entirely consistent with an intent only to ensure that patients received the medicines prescribed for them in good faith by their doctors.

In any event, Plaintiffs are wrong that the opioid epidemic was the “necessary consequence” of Defendants’ shipments. As Defendants have explained elsewhere, the record establishes that, no matter how many pills a distributor ships to pharmacies, those pills will sit on the shelf and have no potential to harm to anyone unless a doctor writes a prescription, a pharmacist dispenses the pills, a patient or third party diverts the pills to illicit use, and an end user misuses the pills in a way that causes harm.<sup>14</sup> With respect to any harm caused by diversion of prescription opioids, the record shows that two additional acts, ***both illegal***, must have occurred: (1) the opioid must have been diverted to illegal use; and (2) someone must have illegally possessed and used the diverted opioid.<sup>15</sup> Only after these four actions—

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First Amendment right to petition the government. *See Opdyke Inv. Co. v. City of Detroit*, 883 F.2d 1265, 1273 (6th Cir. 1989). The doctrine applies regardless of a defendant’s alleged motive. *See, e.g., Noerr*, 365 U.S. at 139 (“The right of the people to inform their representatives in government of their desires with respect to the passage or enforcement of laws cannot properly be made to depend upon their intent in doing so.”); *Sierra Club v. Butz*, 349 F. Supp. 934, 938 (N.D. Cal. 1972) (“All persons, regardless of motor, are guaranteed by the First Amendment the right to seek to influence the government or its officials to adopt a new policy, and they cannot be required to compensate another for loss occasioned by a change in policy should they be successful.”).

<sup>14</sup> *See* Ex. B (Keyes Dep.) at 115:16–116:6 (testifying that pills can only leave a pharmacy through a prescription written by a doctor or illegal means such as illegal sale or theft).

<sup>15</sup> *See, e.g.,* Ex. C (Cox. Dep.) at 47:10–17 (“Q. So is it your understanding then that diversion of pharmaceutical drugs is always illegal? A. Yes. Q. So then the person who diverts a

prescribing, dispensing, illegal diversion, and illicit use—*might* harm occur as a result of the end-users’ criminal activity, addiction, or overdose.

In sum, the most Plaintiffs’ evidence shows is that Defendants delivered prescription medications to licensed pharmacies and hospitals that ordered them to fill valid prescriptions written by physicians based on the then-prevailing standard of care. Plaintiffs therefore cannot prove that Defendants intended to cause a public nuisance.

### **III. Plaintiffs Cannot Establish Negligence by Pointing To Alleged Violations of the CSA**

Plaintiffs’ claims are based on alleged violation of the CSA.<sup>16</sup> Indeed, Plaintiffs fail to explain with any specificity how Defendants’ conduct was unreasonable apart from allegedly violating regulatory provisions of the CSA. While Plaintiffs contend that they “seek to hold Defendants responsible for conduct that violates state law as well as the CSA,”<sup>17</sup> Plaintiffs have acknowledged that the CSA is the foundation of their claims and twice have asked this Court to rule on the duties imposed on Defendants by the CSA.<sup>18</sup> But an alleged violation of the federal CSA cannot provide the basis for Plaintiffs’ public nuisance claims.<sup>19</sup>

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pharmaceutical drug has committed a crime, correct? A. Yes.”); *id.* at 47:22–48:3 (“Q. Just so there’s no confusion, the use or possession of a diverted pharmaceutical drug is a crime, correct? A. Yes.”).

<sup>16</sup> Defendants’ arguments on the application of the CSA are fully set out in Doc. 1087, Defendants’ Memorandum of Law in Opposition to Plaintiffs’ Motion for Partial Summary Judgment Concerning Defendants’ Statutory and Regulatory Duties (“Defs’ Opp. on Duties”), which Defendants hereby incorporate.

<sup>17</sup> Doc. 1075 at p.16, Plaintiffs’ Opp.

<sup>18</sup> Doc. 190, Plaintiffs’ Memorandum of Law in Support of Motion to Adopt Multidistrict Litigation Court’s Order on Defendants’ Controlled Substances Act Duties (“Pls’ Memo on Adopting MDL on Duties”); Doc. 1011, Plaintiffs’ Motion for Partial Summary Judgment Concerning Defendants’ Statutory and Regulatory Duties (“Pls’ MSJ on Duties”).

<sup>19</sup> *See* Doc. 287, Plaintiffs’ Memorandum of Law In Opposition to Defendants’ Motion for Summary Judgment Based on Standing.

**A. The CSA May Not Be Privately Enforced—Neither Directly Nor Through a State Common Law Claim**

Because the CSA may not be privately enforced, Plaintiffs try to cast their claims as arising under the common law of nuisance.<sup>20</sup> This maneuvering does not save Plaintiffs’ claims.

Where Congress has delegated the authority to enforce a statute exclusively to a particular executive department or agency, no one else can enforce the statute either directly (by seeking statutory penalties) or indirectly (by bringing a common law public nuisance action).<sup>21</sup> Contrary to Plaintiffs’ assertion, *Astra USA, Inc. v. Santa Clara County*<sup>22</sup> is directly on point. In *Astra*, a federal statute limited the prices that certain drug manufacturers could charge healthcare facilities.<sup>23</sup> Managed healthcare facilities, believing they were overcharged, sued the drug manufacturers alleging that overcharging under the statutory scheme constituted a breach of the manufacturers’ enrollment contracts and that the facilities, as third-party beneficiaries of those contracts, could recover damages.<sup>24</sup>

The Supreme Court held that the facilities’ common law breach of contract suit was “incompatible with the statutory regime.”<sup>25</sup> In reaching this conclusion, the Court emphasized

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<sup>20</sup> See *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290 (D. Colo. 2010) (collecting cases and holding that the CSA does not create a private right of action); see also *West Virginia v. McKesson Corp.*, Case No. 2:17-03555, Dkt. 21 at 14–15 (S.D. W. Va. Feb. 15, 2018); *McKesson Corp. v. Hembree*, No. 17-CV-323-CK-FHM, 2018 WL 340042, at \*5 (N.D. Okla. Jan. 9, 2018); *Floyd v. Feygin*, No. 507458/17, 2018 WL 6528728, at \*6 (N.Y. Sup. Ct. Dec. 6, 2018) (holding that state-law negligence claim was “preempted” by CSA and DEA regulations).

<sup>21</sup> *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 118 (2011).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 113.

<sup>24</sup> *Id.* at 116.

<sup>25</sup> *Id.* at 113

that Congress assigned to the Secretary of Health and Human Services the exclusive role of enforcing the pricing scheme.<sup>26</sup> Healthcare facilities, the Court reasoned, could not circumvent Congress’ judgment in this regard by asserting common law claims based on alleged violations of the statutory scheme: “If [the healthcare facilities] may not sue under the statute, it would make scant sense to allow them to sue on a form contract implementing the statute, setting out terms identical to those contained in the statute.”<sup>27</sup> The Court went on to explain why authorizing indirect enforcement of the statute would amount to an end-run around Congress’s intent: “[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if [healthcare facilities] could overcome that obstacle by suing to enforce the contract’s ceiling-price obligations instead.”<sup>28</sup>

Here, as in *Astra*, Plaintiffs seek to enforce a statutory scheme, the CSA, that contains no private right of action and enforcement of which is entrusted to a federal agency, the DEA.<sup>29</sup> Allowing Plaintiffs to assert a public nuisance claim premised on Defendants’ alleged violations of the CSA would render meaningless the absence of a private right of action.<sup>30</sup> Here, as in *Astra*, Plaintiffs (improperly) seek to establish a common law claim—public nuisance (whether by proving negligence or, as Plaintiffs say is enough, unlawful conduct)—

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<sup>26</sup> *Id.* at 114.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 118.

<sup>29</sup> *Hickenlooper*, 164 F. Supp. 3d at 1290 (“according to its plain terms, the CSA is a statute enforceable only by the [United States] Attorney General and, by delegation, the Department of Justice.”) (internal quotations and citation omitted); DEA, *Practitioner’s Manual, An Informational Outline of the Controlled Substances Act* 4 (2006 ed.) (The Attorney General has delegated enforcement Authority under the CSA to the DEA).

<sup>30</sup> *See Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994) (permitting a plaintiff to enforce statutory or regulatory duties through common law negligence “would, in effect, be permitting a private cause of action” under the statute).

through proof of violations of a federal statute that Congress has determined may not be privately enforced. Controlling law forbids this. Plaintiffs' only answer to *Astra* is to assert that they base their claims on more than a "mere[ ] violat[ion] [of] the CSA," but also on a violation of "parallel common-law duties."<sup>31</sup> But an argument like that did not save the claims asserted by the plaintiffs in *Astra*, who alleged that the defendants breached a contract and that they suffered harm caused by the defendants' statutory violations. It cannot save Plaintiffs' claims here either.

**B. The CSA and Its Associated Regulations Do Not Impose Duties on the Defendants, Let Alone a Duty Not to Ship Suspicious Orders**

Plaintiffs also falter when they describe what the CSA provides. The CSA provides factors to be considered when making registration determinations, not duties imposing liability on Defendants.<sup>32</sup> Plaintiffs' and the MDL court's reliance on 21 C.F.R. § 1301.71(a) is misplaced because analysis of the regulatory scheme as a whole reveals that these provisions are intended to govern the registration process, not to impose duties on Defendants. *See* 21 C.F.R. § 1301.01 ("Procedures governing the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances pursuant to sections 301–304 and 1007–1008 of the Act (21 U.S.C. 821–824 and 957–958) are set forth generally by those sections and specifically by the sections of this part."). And even if the CSA, as Plaintiffs argue, expressly imposes a duty on Defendants to maintain effective controls against diversion, such a duty does not imply that Defendants had a duty not to ship suspicious orders.<sup>33</sup>

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<sup>31</sup> Doc. 1075 at p.10, Plaintiffs' Opp.

<sup>32</sup> Doc. 1087 at p.5-7, Defs' Opp. on Duties; 21 U.S.C. § 823(b) ("In determining the public interest" for purposes of registration, the statute instructs DEA to consider certain factors, including the applicant's "maintenance of effective controls against diversion.").

<sup>33</sup> Doc. 1087 at pp. 5-9, Defs' Opp. on Duties.



Indeed, as Defendants have explained elsewhere, if the CSA imposes any duties on Defendants, those are not duties owed to *Plaintiffs*.<sup>34</sup>

Plaintiffs say that the fact “[t]hat the DEA is empowered to overlook insubstantial violations of law does not mean that the law has not been violated; it goes only to the consequences of those violations.”<sup>35</sup> That assertion does not help Plaintiffs. Indeed, the DEA’s authority to overlook non-compliance underscores DEA’s exclusive enforcement role and, in turn, further underscores that imposition of tort liability based on purported CSA violations would frustrate the statute’s enforcement scheme.<sup>36</sup> Such interference with the CSA’s statutory scheme is forbidden.<sup>37</sup>

The West Virginia Controlled Substances Act (“WVCSA”) and its implementing regulations are similar to the CSA’s regulatory provisions.<sup>38</sup> Plaintiffs themselves have admitted that similar reasoning applies to both statutory schemes.<sup>39</sup> Accordingly, Plaintiffs cannot seek to impose tort liability on Defendants for alleged violations of the WVCSA and its associated regulations for substantially the same reasons described above.

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<sup>34</sup> Doc. 357 at 6, Defendants’ Reply in Support of Motion for Summary Judgment: Standing.

<sup>35</sup> Doc. 1075 at p.10, Plaintiffs’ Opp.

<sup>36</sup> See *Gonzalez v. Raich*, 545 U.S. 1, 24 (2005) (“The [CSA] is designed to foster the beneficial use of those medications, to prevent their misuse, and to prohibit entirely the possession or use of substances listed in Schedule I, except as a part of a strictly controlled research project.”).

<sup>37</sup> See *Nw. Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO*, 451 U.S. 77, 97 (1981) (courts “may not, in the face of such comprehensive legislative schemes, fashion new remedies that might upset carefully considered legislative programs”) see also *id.* (“the presumption that a remedy was deliberately omitted” is “strongest when Congress has enacted a comprehensive legislative scheme including an integrated system of procedures for enforcement.”).

<sup>38</sup> See W. Va. C.S.R. § 15-2-4; see also W. Va. C.S.R. § 15-2-3 (adopting by reference the requirements of the federal regulations at 21 C.F.R. §§ 1300–1321).

<sup>39</sup> Doc. 1011-1 at p.15, Plaintiffs’ Memorandum of Law in Support of Motion for Partial Summary Judgement Concerning Defendants’ Statutory and Regulatory Duties (The WVCSA “is intended to be consistent with the federal CSA to the fullest extent practicable.”).

### C. Plaintiffs' Claims are Preempted by the CSA

Contrary to what Plaintiffs contend, their claims are not merely “parallel” to the CSA—instead, Plaintiffs seek to borrow standards established in the CSA to impose liability on Defendants.<sup>40</sup> Allowing Plaintiffs to impose state law nuisance liability based on standards borrowed from the CSA would stand as an obstacle to fulfillment of the CSA’s purposes and interfere with the CSA’s enforcement scheme.<sup>41</sup> Plaintiffs’ claims therefore are preempted.<sup>42</sup>

Plaintiffs’ citation to *Wyeth v. Levine*<sup>43</sup> does not advance their argument that the CSA does not preempt their claims. In *Wyeth*, the state law failure-to-warn claim brought by the plaintiff was not premised on the defendant’s alleged violation of federal labeling requirements, but instead on an alleged violation of an independent duty to warn owed to the plaintiff under state law.<sup>44</sup> Here, as explained above, Plaintiffs’ claims rest squarely (and solely) on the violation of federal law. Plaintiffs fail to articulate how Defendants’ conduct was negligent (or unreasonable) beyond alleging that Defendants failed to fulfill duties purportedly imposed by the CSA. “[T]he existence of [this] federal enactment[] is a critical element in their case.”<sup>45</sup>

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<sup>40</sup> Doc. 190, Pls’ Memo on Adopting MDL on Duties; Doc. 1011, Pls’ MSJ on Duties.

<sup>41</sup> See *Gonzalez*, 545 U.S. at 24 (“The [CSA] is designed to foster the beneficial use of those medications ....”).

<sup>42</sup> See *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001).

<sup>43</sup> 555 U.S. 555 (2009).

<sup>44</sup> *Id.*

<sup>45</sup> *Buckman*, 531 U.S. at 353.

Plaintiffs’ attempt to distinguish *Buckman Co. v. Plaintiffs’ Legal Committee*<sup>46</sup> fares no better. There, the Supreme Court held that state law claims are preempted when such claims interfere with the ability of federal regulators to balance statutory objectives:

Given this analytical framework, we hold that the plaintiffs’ state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.<sup>47</sup>

The *Buckman* court further explained how the plaintiffs’ fraud-on-the-agency claims would be in tension with the federal statutory scheme:

In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.<sup>48</sup>

Congress’ intent to preserve state law in the absence of positive conflict with the CSA does not, as Plaintiffs’ suggest, distinguish this case from *Buckman*, where the court held that neither express preemption provisions nor a saving clause impacted its conflict preemption analysis.<sup>49</sup> Here, as in *Buckman*, a federal agency (the DEA) has been empowered by Congress to deter and punish violations of the CSA and is provided ample discretion in exercising that power to achieve a delicate balance of the statutes twin objectives—promoting the beneficial

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<sup>46</sup> 531 U.S. 341 (2001).

<sup>47</sup> *Id.* at 348.

<sup>48</sup> *Id.* at 353.

<sup>49</sup> *Id.* at 352; *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000) (“the saving clause does *not* bar the ordinary working of conflict pre-emption principles”) (original emphasis).

use of controlled medications while combating illicit use. Moreover, here, as in *Buckman*, violation of federal statutory provisions and regulations serves as a “critical element” of Plaintiffs’ claims. Numerous cases have, like *Buckman*, held that state law claims based on the violation of federal law are preempted when they interfere with the ability of regulators to balance statutory objectives.<sup>50</sup>

Plaintiffs’ nuisance suit cannot stand on its own feet. Plaintiffs improperly allege that Defendants’ violations of standards imposed by the CSA constitute an unreasonable interference with a public right. Because Plaintiffs’ claims rest on Defendants’ alleged violation of the CSA, Plaintiffs’ claims are preempted.

### CONCLUSION

For the reasons explained in this reply, and those in Defendants’ opening brief, Doc. 1007-3, the Court should grant summary judgment to Defendants because Plaintiffs cannot establish the fault element of their public nuisance claims.

Dated: October 30, 2020

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<sup>50</sup> *Geier*, 529 U.S. at 863 (holding that a rule of state tort law imposing a duty to install airbags in all cars would present an obstacle to the variety and mix of devices prescribed by federal regulation); *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 944 (6th Cir. 2018), *cert. denied*, No. 19-1246, 2020 WL 5882237 (U.S. Oct. 5, 2020) (holding plaintiff’s claim resting on federal regulation requiring drug manufacturers to ensure the availability of Medication Guides for distribution to patients was preempted); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1207–08 (9th Cir. 2002) (holding that the plaintiff’s state law intentional interference claim arising from defendant’s alleged submission of false information to the Environmental Protection Agency was preempted by the Federal Insecticide, Fungicide, and Rodenticide Act); *Bean v. Upsher-Smith Pharm., Inc.*, No. 4:16-CV-01696-RBH, 2017 WL 4348330, at \*7 (D.S.C. Sept. 29, 2017) *aff’d*, 765 F. App’x 934 (4th Cir. 2019) (“Because the requirement to provide a Medication Guide to distributors is based solely in the requirements of the FDCA and related regulations, and there is no parallel duty to provide a Medication Guide under South Carolina law, Plaintiff’s claims based upon failure to provide a Medication Guide are preempted under *Buckman*.”).

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 30, 2020, the foregoing *Reply in Support of Defendants' Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims* was sent to counsel for the Plaintiffs and Defendants using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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